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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 92/11803
A61B 5/00, G06F 15/20	A1	(43) International Publication Date:	23 July 1992 (23.07.92)

(21) International Application Number: PCT/US92/00298

(22) International Filing Date: 6 January 1992 (06.01.92)

(30) Priority data:
638,258 7 January 1991 (07.01.91) US

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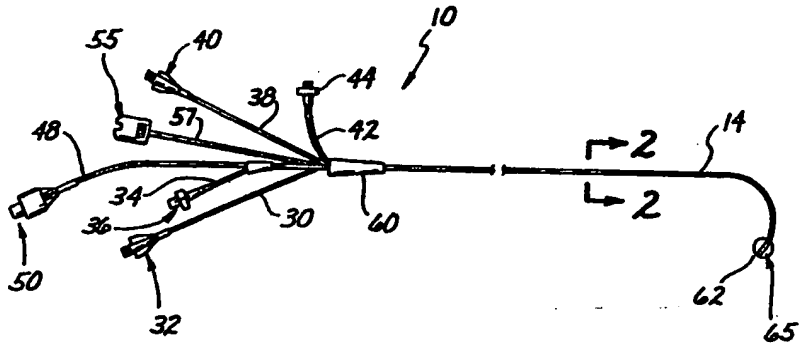
(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CARDIOPULMONARY MONITORING SYSTEM WITH INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR



(57) Abstract

A cardiopulmonary monitoring system (100) transmits and receives optical signals to and from the interior of a blood vessel via a fiberoptic catheter (10). The signals may be processed to obtain a measurement of the blood oxygenation saturation level of the blood within the blood vessel. The cardiopulmonary monitoring system includes a detector which detects optical signals. A detector (402) provides an electrical output signal which has an amplitude that is proportional to the intensity of the detected optical signal transmitted from the blood vessel. The monitoring system (100) further comprises a signal processing device (420), which includes means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first signal quality indicator value based upon the monitored frequency. The monitoring device (100) also monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel and generates a second quality indicator value in response thereto. The monitoring device (100) also monitors the amplitude of the output signal and generates a third signal quality indicator value in response thereto. The three indicator values are then compared, and the highest one is selected to be output as a quality display value. The output quality display value is indicative of the reliability of the blood oxygenation saturation level reading output by the monitoring system.

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CARDIOPULMONARY MONITORING SYSTEM WITH INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR

Field of the Invention

The present invention is related to fiberoptic cardiac catheters.

Background of the Invention

Fiberoptic cardiac catheters are well known in devices which measure the oxygenation of the blood between the heart and the lungs. Typically, light in two or three distinct wavelengths is introduced into the bloodstream by means of transmitting fiberoptic lines. The light signals, (generally in the red and infrared color bands), are reflected and refracted by the blood so that a portion of the light signals are received by sensing fiberoptic lines which are also within the cardiac catheter. The oxygenation of the blood may then be determined from the information obtained from the received signals.

In simplified terms, the oxygenation of the blood is measured by determining the color of the blood using the fiberoptic catheter. As described in U.S. Patent Nos. 4,641,658 and 4,651,741, the oxygenation of the blood may be determined using the information obtained from the backscattering of red (R) and infrared (IR) signals. Because the amplitude of both the R signal and the IR signal is affected by, among other things, artifacts such as clots and flow patterns, the oxygenation of the blood has traditionally been measured by generating an R/IR signal in which the artifacts cancel out. The oxygenation percentage is a known function of the R/IR ratio, and the oxygenation percentage can thus be measured. U.S. Patent Nos. 4,641,658 and 4,651,741 are herein incorporated by reference.

As the blood under test flows about the catheter tip, the amplitude of the backscattered radiation (most notably

the IR radiation) fluctuates as an AC signal in synchronization with the patient's heartbeat. It is believed that this is due, in part, to the turbulence created by eddy currents about the catheter tip as blood flows past the catheter. Generally, turbulent blood scatters more light than stationary blood, so that, as the blood alternately flows and rests with the heart's pumping action, the amplitude of the received IR signal varies accordingly. The pulsatile fluctuations of the IR signal typically exhibit sinusoidal characteristics and are generally smooth with gradual changes in amplitude. In many instances, however, the amplitude of the received IR signal exhibits spiking characteristics wherein a sharp increase in amplitude occurs at each heartbeat. This is often the case when the catheter tip is positioned near the wall of a blood vessel. When the tip of the catheter impacts or closely approaches the wall of a blood vessel, the increased reflectivity of the vessel wall in comparison with the blood itself causes a greater amount of light to be reflected into the receiving fiberoptic line, thereby causing the amplitude of the received signal to sharply increase. Since the vessel wall exhibits reflective characteristics which are not necessarily related to blood oxygen saturation, these substantial fluctuations resulting in greatest part from the reflectance of the vessel wall can introduce inaccuracies into the measurement of blood oxygen.

Various techniques have been used for reducing or eliminating these substantial fluctuations. In one system, the catheter tip is enclosed in a cage-type structure to prevent the tip of the catheter from impacting the vessel wall. While the cage structure may effectively separate the catheter tip from the vessel wall, the structure also greatly increases the tendency for deposits to form on the catheter tip, an undesirable result. In another system, a signal filter removes data above a predetermined threshold

amplitude in an attempt to eliminate any erroneous data. This approach may be effective as long as the artifact is not too severe, or does not last too long. However, if a large portion of the signal readings have to be filtered, there may not be enough good readings to maintain tracking of oxygenation saturation levels.

Some techniques include displaying the IR signal intensity, which requires the user to interpret the display as to whether or not it is normal, and separate on/off alerts for each condition detected. The user, however, has no direct interest in the particular characteristics of the signals that are detected. Instead, the user is concerned with whether or not the blood oxygenation reading is reliable.

Summary of the Invention

The present invention is a cardiopulmonary monitoring system which is connected to a fiberoptic cardiac catheter. The system transmits and receives optical signals to and from the interior of a blood vessel via the fiberoptic catheter. The cardiopulmonary monitoring system comprises a detector for detecting an optical signal transmitted from the blood vessel and for generating an output signal in response thereto. The monitoring system further comprises a signal processing device. The signal processing device includes a first signal processing means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first indicator based upon the monitored frequency.

In a preferred embodiment, the system includes second and third processing means for generating second and third indicators respectively. The system further includes means for sensing the first, second and third indicators and generating a quality display signal in response thereto. In a particularly preferred embodiment, the second

processing means monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel, and the third processing means monitors the amplitude of the output signal.

Another aspect of the present invention encompasses a cardiopulmonary monitoring system which comprises a detector for detecting an optical signal transmitted from the blood vessel and generating an output signal having a waveform in response to the optical signal. The monitoring system comprises a means for recursively generating a variable indicative a waveform characteristic, such as spikes in the waveform, and a means for generating an indicator based upon the variable.

The present invention further encompasses a method for monitoring an optical signal from a cardiopulmonary catheter comprising the steps of: 1) detecting the optical signal and generating a waveform in response thereto, 2) monitoring the spikes in the waveform during a second interval, and 3) utilizing the results of steps 1) and 2) to generate an indicator.

Brief Description of the Drawings

Figure 1 is a plan view of a fiberoptic cardiac catheter used in accordance with the present invention.

Figure 2 is a cross-sectional view of a section of tube of the catheter shown in figure 1.

Figure 3 is a front view of the cardiopulmonary monitoring apparatus of the present invention which shows the details of the display panel.

Figure 4 is a simplified block diagram which shows the processing circuitry used within the cardiopulmonary monitoring system shown in Figure 3.

Figure 5 is a flowchart which shows the overall method of processing cardiopulmonary data in accordance with the present invention.

Figure 6 is a flowchart which details the method used in accordance with the data acquisition and filtering

subroutine block of Figure 5.

Figure 7 is a flowchart which details the method used in accordance with the update quality display signal subroutine block of Figure 5.

Detailed description of the Preferred Embodiment

Figures 1 and 2 show a side view and a cross-sectional view respectively of a fiberoptic cardiac catheter 10 which may be used in accordance with the present invention. The catheter 10 includes an elongated catheter tube 14 having an inflation lumen 16, a distal lumen 18, a thermistor wires lumen 20, an injectate lumen 22, an RV port infusion lumen 24, and a fiberoptic lumen 26. A distal lumen tube 30, having a distal lumen hub 32 attached thereto, is fused to the tube 14 within the distal lumen 18. In a like manner, an inflation lumen tube 34 with an inflation valve 36, an injectate lumen tube 38 with an injectate hub 40, and an RV port infusion tube 42 with an RV port infusion connector 44, are all fused to the tube 14 within the inflation lumen 16, the injectate lumen 22, and the RV port infusion lumen 24 respectively. Thermistor wires (not shown) within a thermistor tube 48 having a thermistor connector 50 attached thereto, extend through the tube 14 within the thermistor wires lumen 20. Fiberoptic lines extend from a fiberoptic oximetry connector 55 within a tube 57. The tube 57 is also fused to the catheter tube 14 so that the fiberoptic lines extend along the length of the catheter tube 14 within the fiberoptic lumen 26.

The catheter tube 14 may be extruded from a suitable biocompatible plastic material. The tube 14 is advantageously flexible and sized to be received within a blood vessel. The tube 14 has a proximal end situated within a flexible jacket 60, and a distal end 62 to which a balloon 65 is connected. The inflation lumen 16 terminates within the balloon 65 so that the balloon 65 may be inflated using the inflation lumen 16. In one preferred embodiment, the catheter 10 is a Swan-Ganz ® oximetry

catheter, model 93A-780H-7.5F.

The fiberoptic lines within the lumen 26 may be single or multi-mode fiberoptic cables and are advantageously constructed to transmit light in the red and infrared frequency spectrum. At the distal end of the tube 14, the fiberoptic lines are exposed so that light may be radiated into, and received from, the bloodstream when the catheter 10 is inserted into a blood vessel. At the opposite end, the fiberoptic lines are optically connected to the fiberoptic oximetry connector 55. The connector 55 may be hooked up to a monitoring device 100 (Fig. 3).

The monitoring device 100 is capable of generating optical signals in the appropriate wavelengths (e.g., 660nm and 810nm) for transmitting along the fiberoptic lines. The monitoring device 100 is also capable of receiving and processing optical signals, so that the backscattered optical signals sensed by the receiving fiberoptic lines may be monitored and measured by the device 100. The monitoring device 100 advantageously includes an output display for presenting significant information to a user. Such information may include a blood oxygenation saturation reading in numerical 105 and graphical form 107, an alarm signal 110 to indicate conditions which may be dangerous for a patient, and a quality display signal 120, which indicates the reliability of the current blood oxygenation reading.

Figure 4 is a simplified block diagram which shows the general circuitry 400 used within the device 100 to process the incoming optical signals, and to output information to the display of the monitoring device 100. The circuitry 400 includes an electro-optical coupler 402 for receiving optical R and IR signals, and outputting corresponding analog electrical signals which have an amplitude that is proportional to the amplitude of the optical signals. The analog electrical signals are then transmitted to a gate array 410, which provides all required timing and control

signals to the analog circuitry, and serves to convert the analog signals to digital signals at a rate of one sample per millisecond. The gate array 410 may pass the data in either a data mode or an offset mode. The gate array 410 is set in the offset mode when it is desired to calculate offset values, used to correct for system offsets, at each gain level. During normal operation of the monitoring system 100, the gate array 410 is set to the data mode, and basically acts as an A/D convertor which averages 50 input data samples at a rate of one sample per millisecond and outputs a two-byte digital value every 50 ms. These digital signals are then transmitted to a microprocessor 420. The microprocessor 420 performs most of the signal processing and calculates output values which are sent to a display driver 430, which in turn drives a display output 435. The microprocessor 420 also has access to a read only memory (ROM) 450 and a random access memory 455.

Figure 5 is a flowchart which shows the overall method of processing the data obtained from the light backscattered from blood within a blood vessel. The method begins in a block 500 and control is transferred to an activity block 510, wherein the monitoring system 100 is initialized and self tests are performed. Such tests include power-up, offset determination of the R and IR signals at each gain level, initiation of a watchdog-timer, and initiation of run-time diagnostics. Once the monitoring system has been initialized and the watchdog-timer and run-time diagnostics are running, control passes to a subroutine block 520, wherein the data from the receiving fiberoptic line is acquired and filtered.

Basically, within the subroutine block 520, the optical data is converted into electrical signals by the optical coupler 402. These signals are then converted into digital signals via the gate array 410. The gate array 410 then outputs these signals to the microprocessor 420 wherein the digitized signals are filtered and averaged.

Initially, a baseline value and a threshold value are calculated, and those digital signals which are in excess of the calculated threshold value are clipped, so that they are equal to the threshold value. That is, the values which exceed the threshold value are assigned the value of the threshold, while those values which are not in excess of the threshold value remain unchanged. These values are then transmitted to a series of filters and averagers to provide values appropriate for calculating the blood oxygenation saturation level, as well as the blood flow rate. The subroutine block 520 will be described in greater detail in reference to Figure 6 below.

Once the data has been acquired and filtered in the subroutine block 520, control passes to an activity block 530, wherein the cardiopulmonary monitoring system 100 is calibrated and updated. The monitoring system 100 may be calibrated in two ways: in vitro, or in vivo. This calibration and update technique is described in detail in U.S. Patent No.4,651,741. Once calibration has occurred in the activity block 530, control passes to an activity block 540.

In the activity block 540, the value of the blood oxygenation saturation level is calculated and displayed. The blood oxygenation saturation level, S, may be calculated as:

$$S = AX^2 - BX + C - D/X \qquad (1)$$

where A, B, C, and D are constants determined by the design of the catheter 10, and X is calculated as:

$$X = (IROUT/REDOUT)*M - Z \qquad (2)$$

where M and Z are constants determined at calibration, and R and IR are the amplitudes of the filtered red and infrared digital signals respectively. The value of the

blood oxygenation saturation level, S, is then output to the numerical display 105 and the graphical display 107 (Fig. 3).

Once the value of the blood oxygenation saturation level has been out put to the displays 105, 107, control passes to an activity block 550, wherein any alarm conditions are checked. Such alarm conditions include a high/low saturation alarm, a saturation "out-of-range" alert, and a light "out-of-range" alert. The high/low saturation alarm indicates that the blood oxygenation saturation level of the patient has exceeded or dipped below certain operator determined safety levels. The saturation "out-of-range" alert is activated when the value of X is above or below certain predetermined values (e.g., 0.54 and 2.57 in one embodiment). Finally, the light "out-of-range" alert is activated when the R or IR signal is either overscale, or too small to depend upon an adequate signal-to-noise ratio. For example, overscale may occur when the amplitude of one of the received light signals needs to be brought down to a lower gain, but the gain scale is already on the lowest level. The low-light alert is activated when the mean digital value of either the R or IR signals over a period of two seconds is below a certain digital value, and the gain scale is set to the highest level. If any of the alarm conditions has been activated, a flag is set to indicate which alarm has been activated. Control then passes to a decision block 555 wherein a test is performed to determine if any of the alarms have been activated. If so, then control passes to an activity block 560, wherein the appropriate alarm display is activated, and control is then passed to a subroutine block 570.

If no alarms have been activated, then control passes directly from the decision block 555 to the subroutine block 570, wherein a quality display signal is updated. The quality display signal indicates the reliability of the

blood oxygenation saturation level readings output by the monitoring system 100. In a preferred embodiment, the quality display signal assumes values from one to four, wherein each value is indicative of the quality of the saturation reading. A quality display signal value of "1" indicates that the blood oxygenation saturation level readings are normal, and have an accuracy of +/- 2%. A value of "2" indicates that the saturation readings are moderately degraded, and that the user may wish to adjust the catheter 10 or monitoring system 100 to obtain more accurate readings. A value of "3" indicates that the saturation readings are significantly degraded and the probability of significant errors is increasing. At a value of "3" corrective action is suggested. A value of "4" indicates that the saturation readings are very significantly degraded, and should not be relied upon. When the quality display signal is at level "4," corrective action is strongly recommended. The quality display signal is produced by selecting the highest of three indicator values, wherein each indicator value assumes a value of one to four. In one embodiment, these three indicators are functions of 1) the frequency of clipping exhibited by the R and IR signals, 2) the calculated rate of blood flow in the host vessel, and 3) the shift in intensity of the IR signal over successive half second intervals. The method of updating the quality display signal is described in detail with reference to Figure 7 below. Once the quality display signal is updated in the subroutine block 570, control returns to the activity block 540, wherein the blood oxygenation saturation level is again calculated. This process is repeated continuously to provide suitable monitoring of the blood oxygenation saturation level while the catheter 10 is in place within a patient.

Figure 6 is a flowchart which details the method of acquiring and filtering data within the subroutine block 520. Due to the size of the flowchart, a first portion of

the flowchart is shown on a drawing sheet labeled 6A, and a second portion of the flowchart is shown on a drawing sheet labeled 6B. The method begins in a begin block 600 and control passes to a decision block 602 wherein a test is performed to determine if the gate array 410 is in the offset mode. If the gate array is in the offset mode, control passes to an activity block 604 wherein the offset values of the R and IR signals are calculated at each gain range. This is advantageously done by reading in 500 successive input bits and calculating the offset value as:

$$OFFSET = INT(51200*(N1-1)/(499-N0)) \quad (3)$$

where N1 is the number of digital 1's within the 500 bit sample, and N0 is the number of leading and trailing zero's (the number of zero's before the first 1 and after the last 1). The calculated offset value for the R signal is designated as OSRED, while the calculated offset value for the IR signal is designated as OSIR. In a preferred embodiment, an automatic gain control AGC having gain level values of 1, 4, 16, and 64 is employed which adjusts the system gain as a function of the light intensities of the R and IR signals. Thus, an offset value is calculated as described above for each gain level. Control then passes to an activity block 606 wherein the offset values for each gain level are stored in the RAM 450. Control then returns to the decision block 602. Once the gate array is no longer in the offset mode, control passes to an activity block 610 thereby indicating that the gate array 410 is in the data mode.

In the block 610, two-byte integer values (representative of the R and IR signal intensities) obtained from the gate array 410 at each 50 ms interval are multiplied by a gain value of 64. The full scale value (that is the maximum allowable value) of the integer values is 800 so that, after multiplication, the new full scale

value is 51200. These new upscaled integer values are assigned to the variables RED and IRED. Once the new integer values representing the R and IR signal intensities are determined, control passes to an activity block 612.

In the activity block 612, initial maximum threshold values are set for both the R and IR signal values. These threshold values are used within a clipping subroutine, generally designated as a clipper 611, and are updated periodically. In the clipper 611, the digital values representing the intensities of the R and IR signals are filtered so that those values which fall above the maximum threshold value are assigned the same value as the threshold while those values that are not in excess of the threshold value remain unchanged. At the same time, the values of the thresholds are periodically adjusted in response to the average amplitude of the R and IR signals. Once the initial values are set within the activity block 612, control passes to an activity block 614, wherein the most recent limit values for the R and IR signals are calculated respectively as:

$$LIMRNEW = AVE2R + INT(REDOUT*3/8) \quad (4)$$

$$LIMINEW = AVE2IR + INT(IROUT*3/8) \quad (5)$$

where the values of AVE2R and AVE2IR, and REDOUT and IROUT are feedback values from the output of the processing routine. Control then passes to an activity block 616, wherein a limiting value LIMMIN is calculated for each of the R and IR signals as a value, LORLOW, times 11/16. The value LOWROW is the light out-of-range value (the value which indicates that the R or IR signal intensity is too low for a given gain level) which may be determined in accordance with system requirements. However, if the gain scale (i.e., 1, 4, 16, or 64) is at 64, then the value of LIMMIN is calculated as LORLOW*11/8. Once the limiting

value LIMMIN has been calculated, control passes to a decision block 618, wherein a test is performed to determine if the value of LIMRNEW is less than the limit value LIMMIN. If so, control passes to an activity block 620, wherein the value of LIMRNEW is set to the value of LIMMIN and control then passes to a decision block 622. If the value of LIMRNEW is not less than the value of LIMMIN, then control passes directly to the decision block 622, wherein a test is performed to determine if the value of LIMINEW is less than the value of LIMMIN. If so, control passes to an activity block 624, wherein the value of LIMINEW is set to the value of LIMMIN, and control then passes to a decision block 626. If the value of LIMINEW is not less than the value of LIMMIN, then control passes directly to the decision block 626, wherein a test is performed to determine if the number of clipped values (NC) over the last 500 ms update period (the time necessary to average ten signal values each of the R and IR signals) is equal to 0 or 20 (the minimum or maximum values which NC may assume).

If the value of NC is not equal to 0 or 20, then control passes to an activity block 628, wherein the new threshold values for the R and IR signals are calculated as:

$$LIMRED = INT[(3*LIMRED + LIMRNEW)/4] \quad (6)$$

$$LIMIR = INT[(3*LIMIR + LIMINEW)/4] \quad (7)$$

so that, in essence, a weighted average is calculated to determine the new threshold as a function of the old threshold value and the most recent limit value. If the value of NC is equal to zero or 20, this indicates that the old threshold values should be radically altered, and control passes instead to an activity block 630, wherein the new R and IR threshold values are directly assigned the

values of LIMRNEW and LIMINEW respectively. This initialization of the values of LIMRNEW and LIMINEW serves to decrease settling time so that the calculated limits do not take a long time to reach their appropriate values when the monitoring system is first turned on.

Once the new threshold values have been determined, a fresh sample of 20 signal values (10 R and 10 IR) are filtered. To accomplish this, control passes to a decision block 634 wherein a test is performed to determine if the digital value corresponding to the signal intensity of the R signal, RED, is greater than the newly determined threshold LIMRED. If so, then the output of the R clipper, which shall be designated as the variable E2RED, is assigned the value of the threshold, LIMRED, and NC is incremented by one in the activity block 636. If the value of RED is not greater than the threshold LIMRED, then the output E2RED of the R clipper retains the value of the input, (i.e., E2RED = RED). In a similar manner, the digital value representing the input IR signal is clipped. Control passes to a decision block 642, wherein a test is performed to determine if the value of IRED is greater than the value of the threshold LIMIR. If so, then control passes to an activity block 646, wherein the output of the IR clipper, E2IR is assigned the value of the threshold LIMIR, and the value of NC is incremented by one. If the value of IRED is not greater than the value of LIMIR, then control passes instead to an activity block 644, where E2IR is assigned the value of the input, IRED. Thus, each of the digital values input to the clipper 611 retains its original value or is assigned a new value that is equal to the threshold value.

Once the values have been clipped, control passes from either block 644 or 646 to an activity block 650, wherein the digital values output from the clipper are filtered and averaged. The general procedure followed within the filtering and averaging activity blocks may be

described in program form as follows:

```
DO;
    SUM = 0;
    DO  I = 1 TO N;
        G = G -F + E;
        F = INT(G/K);
        SUM = SUM + F;
        END;
    AVE = INT(SUM/N);
    END;
```

where N represents the number of values being averaged, E is the input variable, G is an intermediate filtering variable, K is a filtering constant, F is the filter output value, and AVE is the average value output. In the filtering and averaging activity block 650, the number of samples being averaged is 10 (N = 10) and the value of the filtering constant K is 32. Thus, assuming an input value every 50 ms, an F value is output every 50 ms, an AVE value is output every 500 ms (10 * 50 ms), and the filter time constant is 1.6 seconds (32 * 50 ms). Note that during in vitro calibration, the time constant is usually smaller (e.g., 400 ms corresponding to K = 8). Therefore, within the activity block 650, an F2 value is output every 50 ms, and an AVE2 value is output every 500 ms for both the R and IR signals.

Once the signals are averaged and filtered in the block 650, control passes to an activity block 654, wherein final output values of the R and IR signals are calculated by subtracting previously determined offset values, OSRED and OSIR, as follows:

$$REDOUT = AVE2R - OSRED \quad (8)$$

$$IROUT = AVE2IR - OSIR \quad (9)$$

Note that the values AVE2R, AVE2IR, REDOUT, and IROUT are fed back to the clipper so that they may be used to calculate the new limit values, LIMRNEW and LIMINEW, which are used to adjust the threshold levels. The values of REDOUT and IROUT are also used to calculate the blood oxygenation saturation level within the activity block 540 of Figure 5. Once REDOUT and IROUT are calculated within the activity block 654, control then passes to an activity block 658, wherein the values of REDOUT and IROUT are stored within the RAM memory 450.

Control then passes to an activity block 662, wherein a difference signal, E3IR, is generated by subtracting the filtered IR value, F2IR, from the value, E2IR, output from the IR clipper, and taking the absolute value (i.e., E3IR = ABS(E2IR - F2IR)). This difference signal may be used to calculate a cardiac flow monitor value, CFM, that is indicative of the rate of blood flow past the catheter 10 within a blood vessel. Note that only the IR signal is used to indicate the rate of blood flow past the catheter. Once the difference signal E3IR is calculated, control passes to an activity block 668, wherein the signal E3IR, which is produced every 50 ms, is filtered and averaged according to a similar method described in accordance with the activity block 650 (i.e., K=32, and N=10). Thus, an F3 value is generated every 50 ms, and an AVE3 value is generated every 500 ms. Control then passes to an activity block 672, wherein an index value E4 is calculated as AVE3/IROUT every 500 ms. The signal E4 is then filtered and averaged within an activity block 676.

The filtering done in the activity block 676 is slightly different than the filtering described in accordance with the activity block 650. In particular, the values of N and K are 4 and 16 respectively. Also, since the incoming data (i.e., E4) is fractional, the program steps:

$$G = G - F + E; \quad (10)$$

$$F = INT(G/K); \quad (11)$$

in the filtering program described above are replaced with a single step:

$$F4 = F4 + (E4 - F4)/K \quad (12)$$

to allow for fractional values at the output. The value of AVE4 which is calculated every 2 seconds is then assigned as the CFM value within an activity block 680. Control then passes out of the subroutine block 520 and proceeds to the calibration and update block 530 as shown in Figure 5.

Figure 7 is a flowchart which details the method used in accordance with the update quality display signal subroutine 570 of Figure 5. The method initiates in a begin block 700 and proceeds to an activity block 710, wherein the intensity shift (IS) signal quality indicator value is determined. This value is determined as a function of a baseline level as will be discussed below. Once the IS quality indicator is determined in the activity block 710, control passes to an activity block 720, wherein the cardiac flow monitor (CFM) indicator value is determined. This value is a function of the CFM index value, AVE4. Control then passes to an activity block 730, wherein a clipping frequency indicator (CFI) value is determined as a function of the last indicator value as well as the number of clips NC within the last 500 ms update cycle. Control then passes to an activity block 740, wherein the highest indicator value of the three indicators (i.e., IS, CFM, and CFI) is selected as the quality display signal. This signal 120 is displayed as a bar graph on the display panel of the monitoring apparatus 100 shown in Figure 3. Recall that each of the three indicators assumes a value of 1 to 4, so that the range of

values of the quality display signal is also 1 to 4. Control then returns to the activity block 710, and the cycle repeats. Note that each indicator value is determined at 2 second update cycles so that the quality display signal is also updated every 2 seconds. A detailed account of the procedure for determining the indicator values for the IS, CFM, and CFI signals follows.

Intensity Shift:

The IS value is based upon the IROUT signal relative to a baseline value. The baseline value is obtained or updated at each calibration or hematocrit update. To obtain the baseline value, a period of approximately 12 seconds is allowed to pass after the monitoring system initiates operation. Following this delay period, the next 16 values (corresponding to 8 seconds) of AVE2IR are averaged. This eight second average is then normalized by multiplying by 64, and dividing by the present gain level to determine the baseline value. Note that the monitoring system includes an automatic gain control (AGC) system to retain accuracy over an extended range of light intensities transmitted by the fiber optic cardiac catheter 10. In a preferred embodiment the four gain levels are 1, 4, 16, and 64. Thus, if the eight second average is determined to be a digital value of 12608, and the monitoring system is presently operating at a gain level of 16, the baseline value would be calculated as (64*12608/16) or 50432.

Large variations from this calculated baseline are indicative of large intensity shifts in the IR signal which may be due to kinks in the fiberoptic lines within the catheter 10, so that the level of the SI indicator increases as the IROUT signal increases in variation relative to the calculated baseline value. In particular, the IS level is determined from the percent change from the baseline and the following limits:

LEVEL 1: 0.67 < IROUT/BASE < 1.50
LEVEL 2: 0.5< IROUT/BASE <0.67, OR 1.5< IROUT/BASE <2.0
LEVEL 3: 0.4< IROUT/BASE <0.50, OR 2.0< IROUT/BASE <2.5
LEVEL 4: IROUT/BASE < 0.40, OR 2.50 < IROUT/BASE

Thus, if the value of the ratio IROUT/BASE is 0.45, then an IS indicator value of 3 will be generated.

Cardiac Flow Monitor:

The calculation of the CFM index, AVE4, is described in detail with reference to the flowchart of Figure 6. Within each 2 second display cycle, the CFM indicator level is determined by converting the value of AVE4 to percent and comparing it to the following limits:

LEVEL 1: 4.5% TO 15%
LEVEL 2: 4.0% TO 4.5% OR 15% TO 18%
LEVEL 3: 3.5% TO 4.0% OR 18% TO 22%
LEVEL 4: LESS THAN 3.5% OR GREATER THAN 22%

Thus if the value of AVE4*100 = 12, then the CFM indicator will be set to a value of 1.

Clipping Frequency Indicator:

The CFI value is determined as a function of the number of clipped values (NC) in the last 500 ms update cycle as well as the last CFI value. At each CFM level, local variables Z, UP, and DN are assigned set values. Another local variable W is then calculated as a function of the last W value, NC and Z. The CFI level is then adjusted as a function of the value of W. In a preferred embodiment, the CFI level is determined according to the following procedure:

Initially, the local variables Z, UP, and DN are set, as a function of the last CFI level.

IF CFI = 1, THEN Z=6, UP=49, and DN=0;
IF CFI = 2, THEN Z=10, UP=104, and DN=11;
IF CFI = 3, THEN Z=14, UP=164, and DN=51;
IF CFI = 4, THEN Z=18, UP=175, and DN=101;

The value of the variable W is then calculated as:

$$W = W_p + 4*NC - Z \quad (13)$$

Where W_p is the value of W for the preceding 500 ms time period. Thus, the calculation of the value W is recursive in that the prior value of W is used as an input value for calculating the current value of W. If the calculated value of W is less than zero, then W is assigned a value of zero. If the calculated value of W exceeds 175, then W is assigned a value of 175. This is done to insure that W does not fall outside of the acceptable range. If the value of W is greater than the current value of UP, then this indicates that the blood oxygenation saturation level reading has become less reliable, and the CFI value is incremented by one. However, if the value of W is less than the current value of DN, this indicates that the blood oxygenation saturation level reading has become more reliable, and the CFI level is decremented by one. If the value of W falls between the current values of UP and DN, then the CFI value remains the same. In this manner the CFI level may be determined.

Once the indicator levels have been determined for the IS, CFM and CFI conditions, the final quality display signal is determined as the highest of the three, and output as a bar graph display 120 on the display panel of the monitoring system 100. Thus, a method and apparatus are provided for the monitoring of the reliability of the blood oxygenation saturation level reading.

The invention may be embodied in other specific forms

without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto; and

a signal processing device comprising first signal processing means for (i) comparing the amplitude of said output signal with a threshold amplitude value, (ii) monitoring the frequency with which said output signal exceeds the threshold value during a selected interval of time and (iii) generating a first indicator based on said frequency.

2. The apparatus of Claim 1, wherein the value of said first indicator for said selected interval of time is based on the value of the first indicator during a preceding interval of time.

3. The apparatus of Claim 1, wherein the first indicator for said selected time interval is dependent on a variable W, said variable W being a function of (i) the variable W for a preceding interval of time, (ii) the frequency with which the output signal exceeds the threshold value during the selected time interval, and (iii) a variable Z which is function of the value of the first indicator during the preceding interval of time.

4. The apparatus of Claim 3, wherein the value of the first indicator for the selected time interval remains equal to the value of the first indicator for the preceding time interval unless the variable W is outside of a predetermined range, said predetermined range being a function of the value of the first indicator S for the preceding time interval.

5. The apparatus of Claim 1, wherein said signal processing device additionally comprises second signal processing means for generating a second indicator signal.

6. The apparatus of Claim 5, wherein said signal processing device additionally comprises third signal processing means for generating a third indicator.

7. The apparatus of Claim 6, additionally comprising means for sensing said first, second, and third indicators and responsively generating a display signal.

8. The apparatus of Claim 7, wherein said display signal has a value corresponding to the highest of said first, second, or third indicators.

9. The apparatus of Claim 5, wherein said second signal processing means monitors the magnitude of variations in said output signal caused by pulsatile blood flow through said blood vessel.

10. The apparatus of Claim 6, wherein said third signal processing means monitors the amplitude of said output signal.

11. A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto, said output signal having a waveform;

means for recursively generating a variable indicative of a characteristic of said waveform; and

means for generating an indicator based on said variable.

12. The apparatus of claim 11, wherein said waveform characteristic comprises spikes in said waveform.

13. A method of monitoring an optical signal from a cardiopulmonary catheter, comprising:

detecting said optical signal and generating a

waveform in response thereto;

monitoring spikes in said waveform during a first time interval;

monitoring spikes in said waveform during a second interval; and

utilizing the results of steps (b) and (c) to generate an indicator.

14. The method of Claim 13, additionally comprising the step of comparing the indicator with another indicator and generating a display signal based on the results of the comparison.

15. The method of Claim 14, wherein the display signal has a value corresponding to the value of the highest of said indicators.

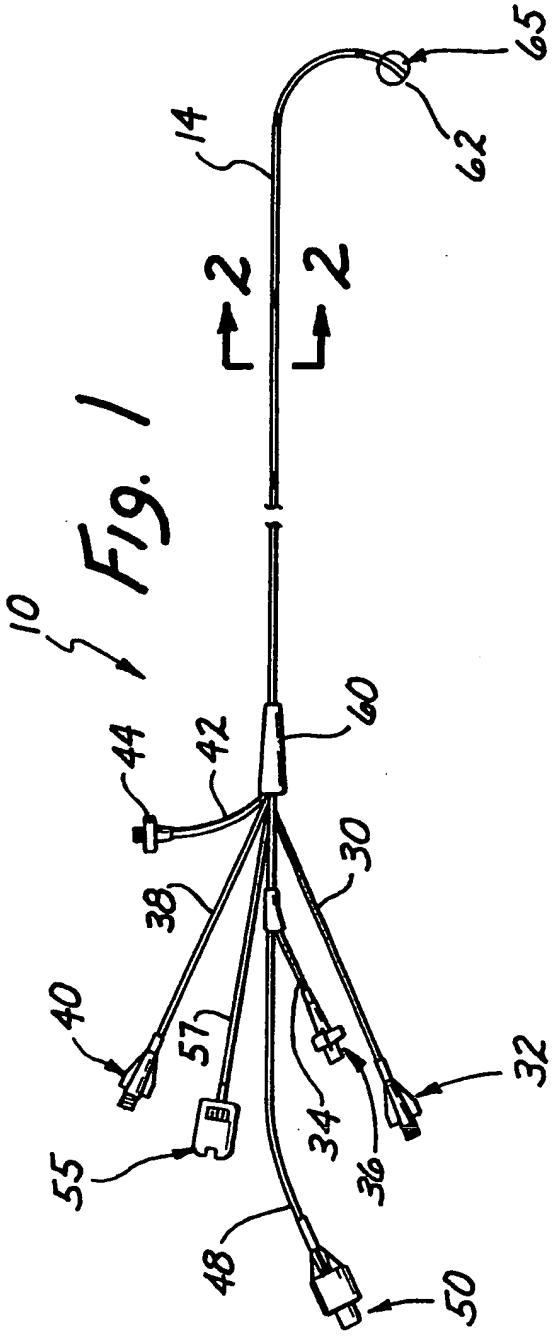


Fig. 1

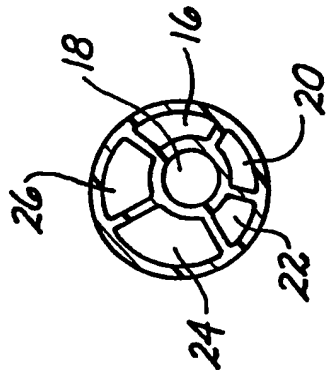


Fig. 2

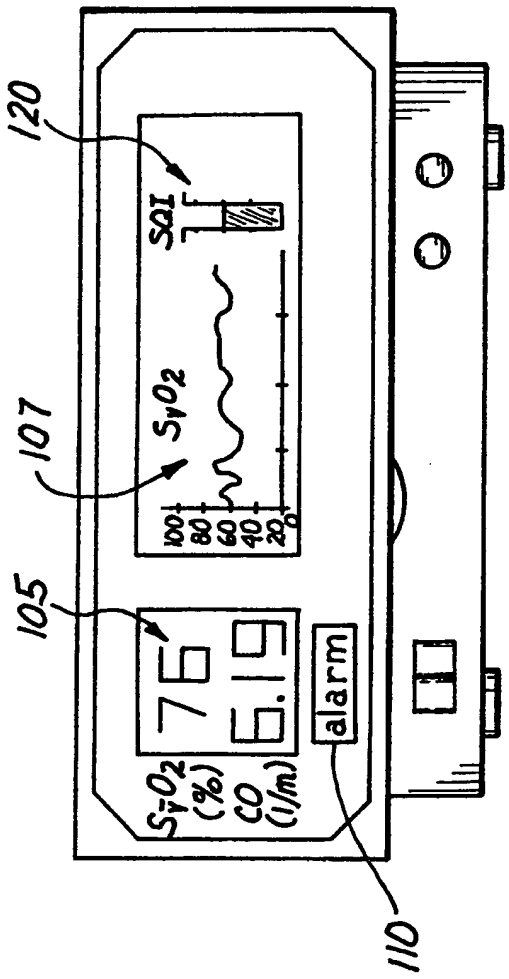


Fig. 3

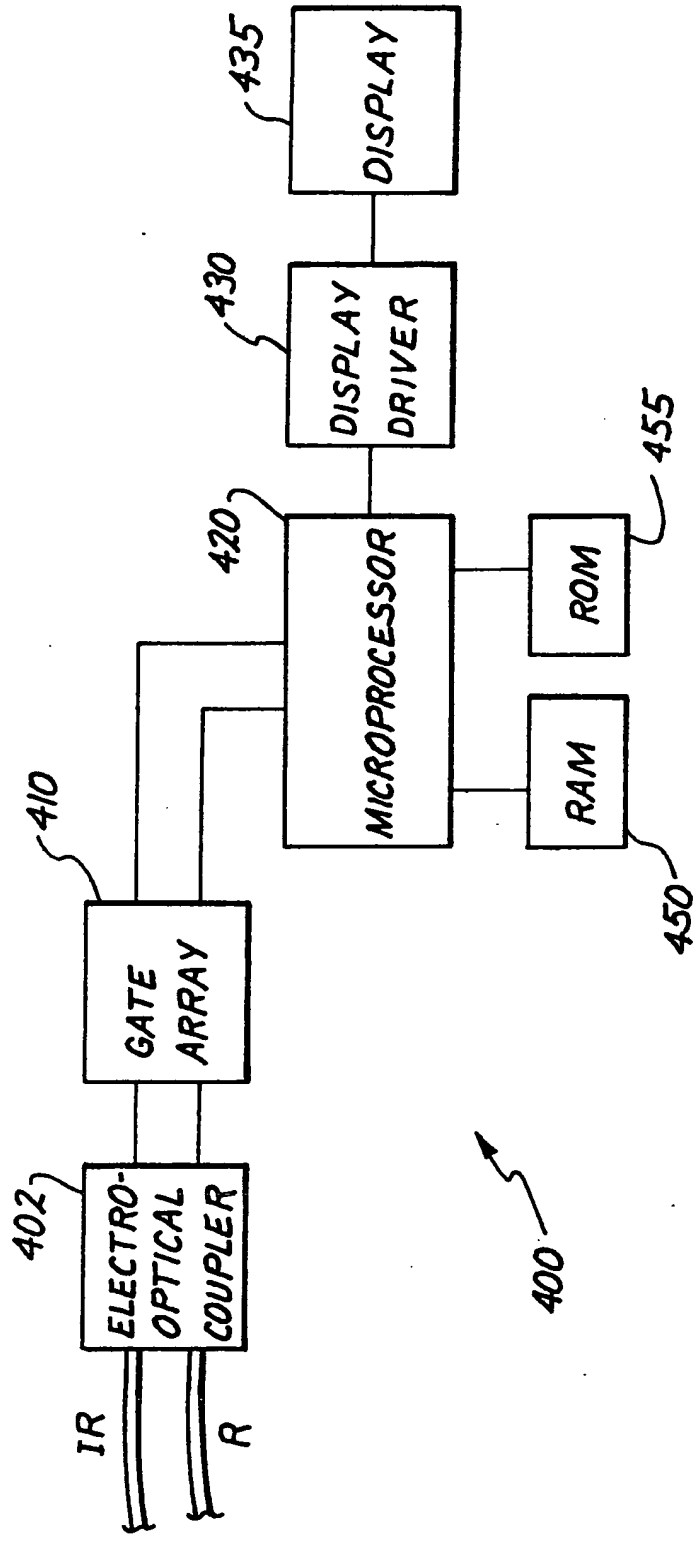

435
DISPLAY
430
DISPLAY DRIVER
420
MICROPROCESSOR
455
ROM
450
RAM
410
GATE ARRAY
402
ELECTRO-OPTICAL COUPLER
IR
R
400

Fig. 4

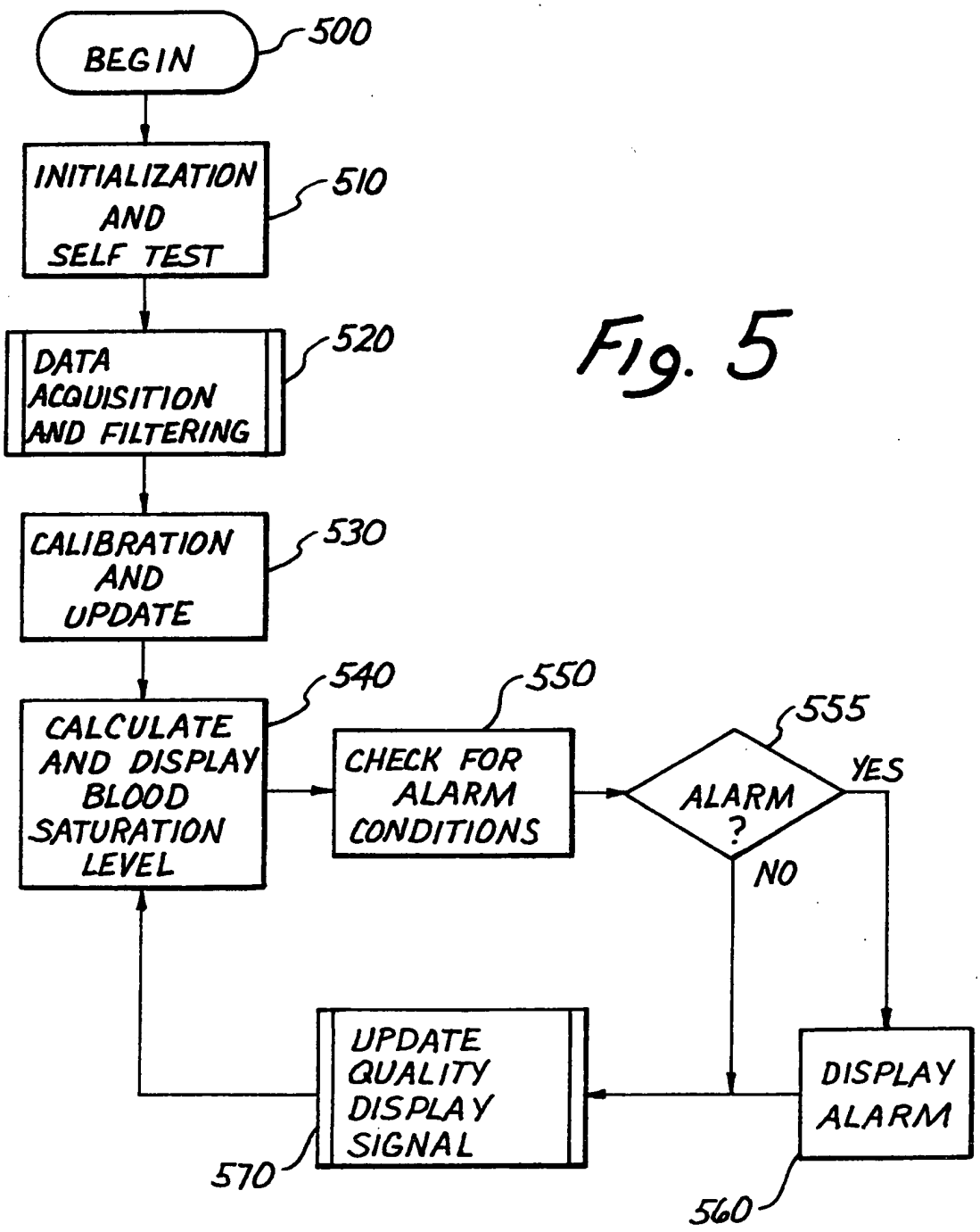
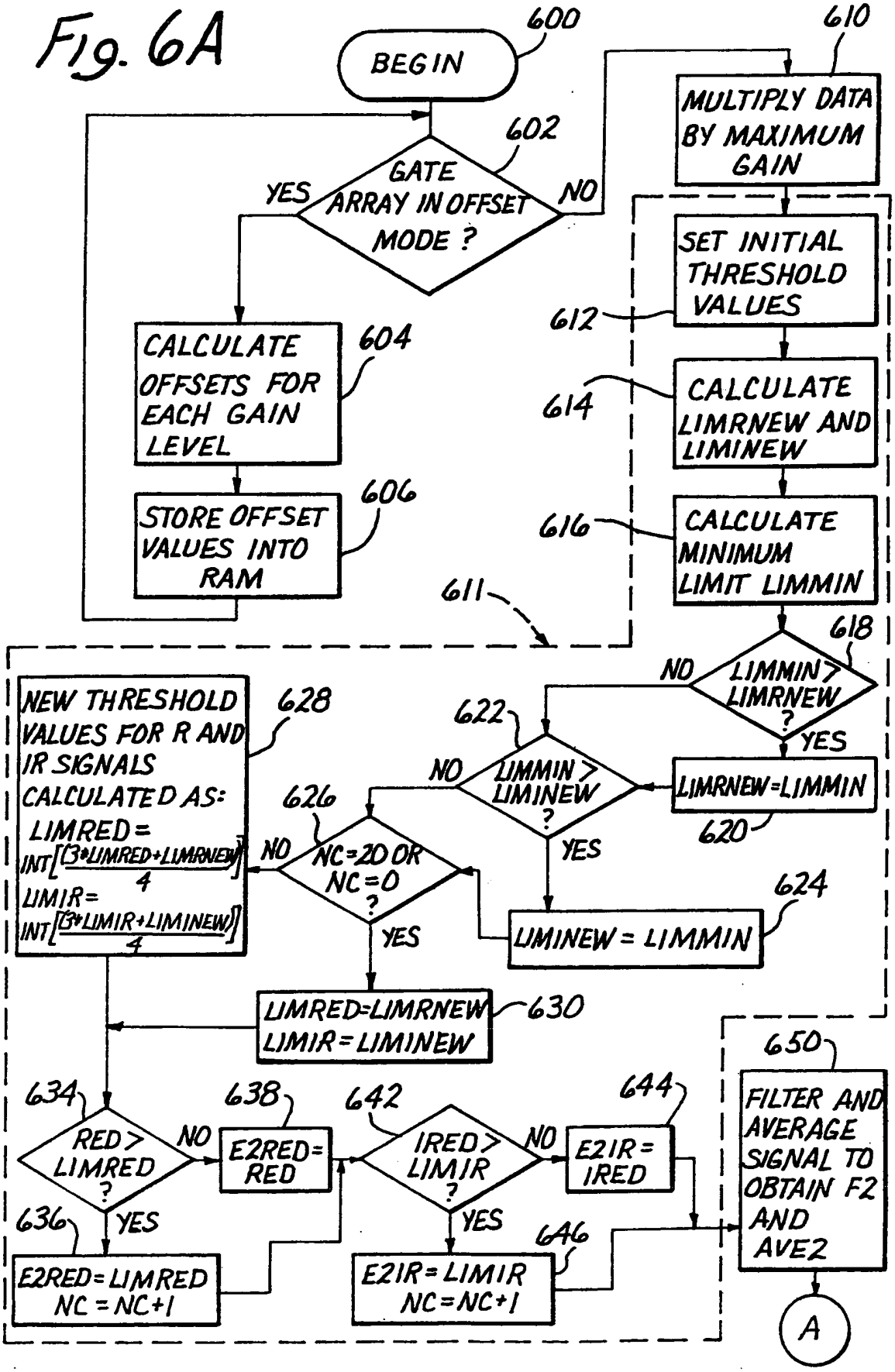

BEGIN
500
INITIALIZATION AND SELF TEST
510
DATA ACQUISITION AND FILTERING
520
CALIBRATION AND UPDATE
530
CALCULATE AND DISPLAY BLOOD SATURATION LEVEL
540
CHECK FOR ALARM CONDITIONS
550
ALARM ?
555
YES
NO
UPDATE QUALITY DISPLAY SIGNAL
570
DISPLAY ALARM
560

Fig. 5

Fig. 6A


BEGIN
600
GATE ARRAY IN OFFSET MODE ?
602
YES
NO
CALCULATE OFFSETS FOR EACH GAIN LEVEL
604
STORE OFFSET VALUES INTO RAM
606
MULTIPLY DATA BY MAXIMUM GAIN
610
SET INITIAL THRESHOLD VALUES
612
CALCULATE LIMRNEW AND LIMINEW
614
CALCULATE MINIMUM LIMIT LIMMIN
616
611
LIMMIN > LIMRNEW ?
618
NO
YES
LIMRNEW=LIMMIN
620
LIMMIN > LIMINEW ?
622
NO
YES
LIMINEW = LIMMIN
624
NC=20 OR NC=0 ?
626
NO
YES
NEW THRESHOLD VALUES FOR R AND IR SIGNALS CALCULATED AS:
LIMRED = INT[(3*LIMRED+LIMRNEW)/4]
LIMIR = INT[(3*LIMIR+LIMINEW)/4]
628
LIMRED=LIMRNEW
LIMIR=LIMINEW
630
RED > LIMRED ?
634
NO
YES
E2RED=LIMRED
NC=NC+1
636
E2RED=RED
638
IRED > LIMIR ?
642
NO
YES
E2IR=LIMIR
NC=NC+1
646
E2IR=IRED
644
FILTER AND AVERAGE SIGNAL TO OBTAIN F2 AND AVE2
650
A

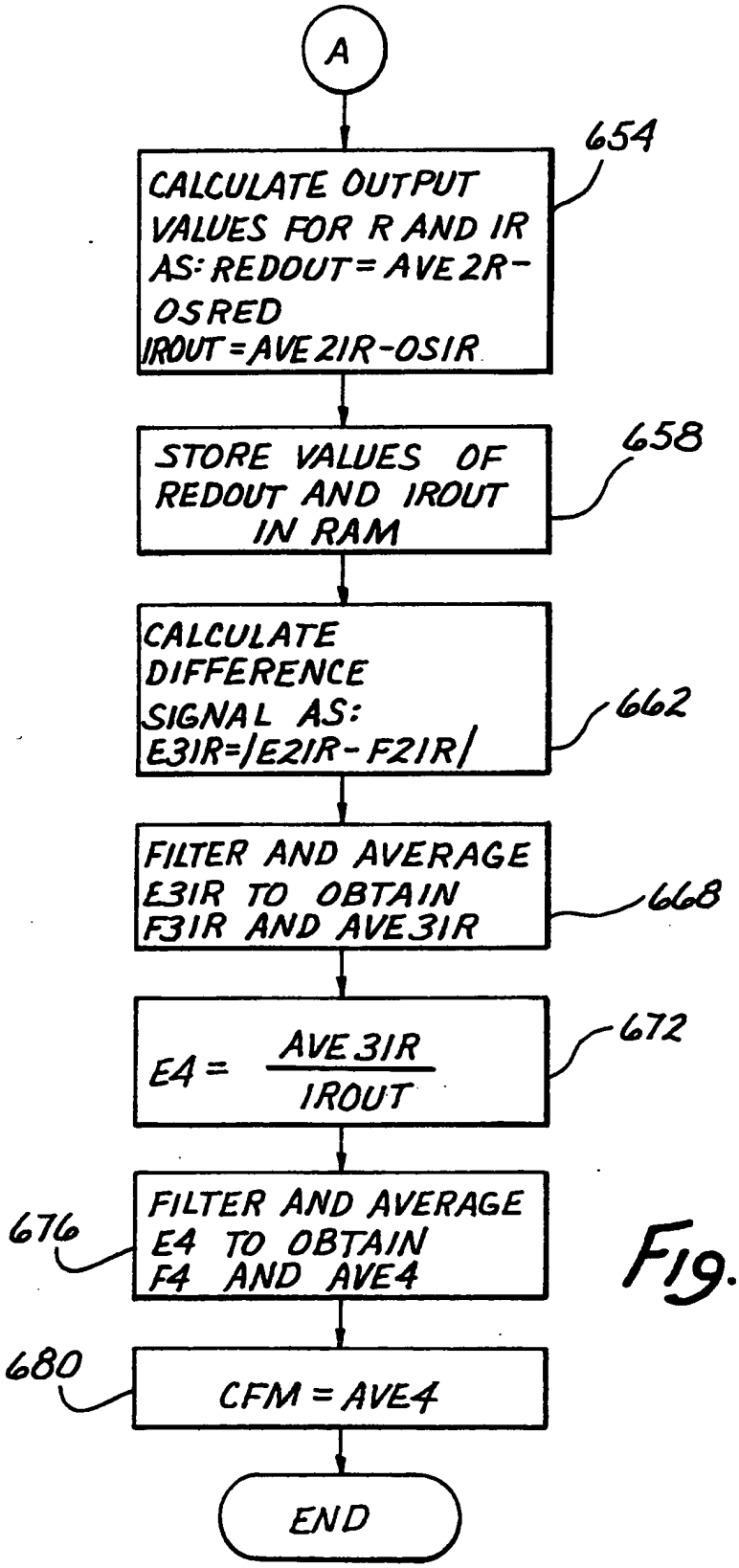

A
654
CALCULATE OUTPUT VALUES FOR R AND IR AS: REDOUT = AVE2R - OSRED
IROUT = AVE2IR - OSIR
658
STORE VALUES OF REDOUT AND IROUT IN RAM
662
CALCULATE DIFFERENCE SIGNAL AS: E3IR = /E2IR - F2IR/
668
FILTER AND AVERAGE E3IR TO OBTAIN F3IR AND AVE3IR
672
E4 = AVE3IR / IROUT
676
FILTER AND AVERAGE E4 TO OBTAIN F4 AND AVE4
680
CFM = AVE4
END

Fig. 6B

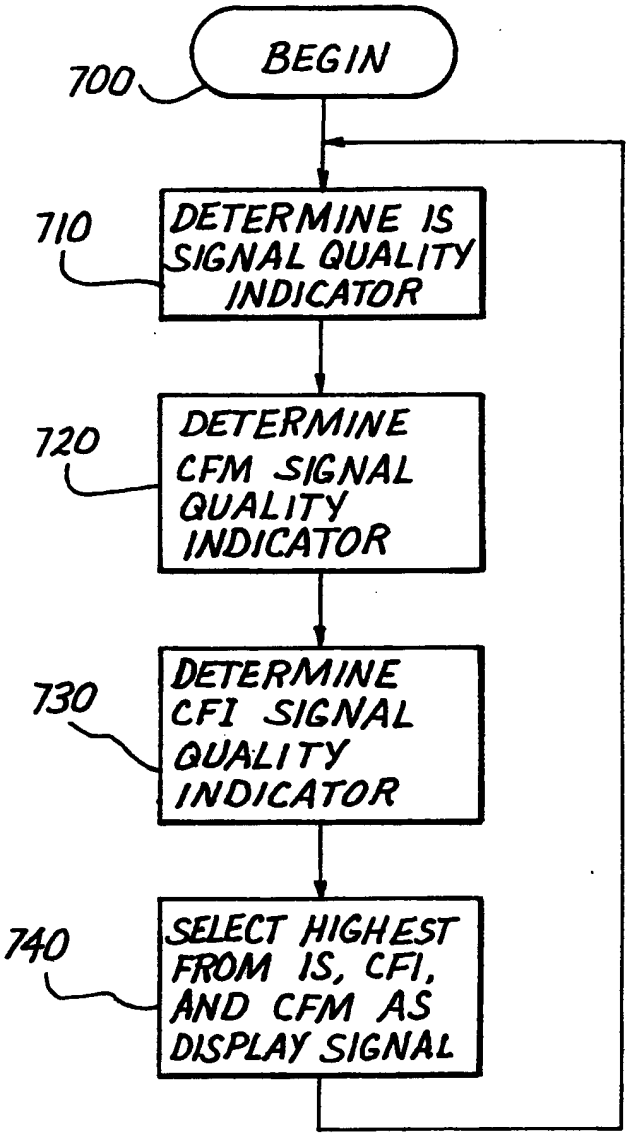

BEGIN
700
DETERMINE IS SIGNAL QUALITY INDICATOR
710
DETERMINE CFM SIGNAL QUALITY INDICATOR
720
DETERMINE CFI SIGNAL QUALITY INDICATOR
730
SELECT HIGHEST FROM IS, CFI, AND CFM AS DISPLAY SIGNAL
740

Fig. 7

INTERNATIONAL SEARCH REPORT

PCT/US 92/00298

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/00; G06F15/20

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; G06F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	WO,A,8 201 948 (OXIMETRIC INC.) 10 June 1982	1,2,11, 12,13
A	see abstract see page 1, line 27 - page 3, line 29 see page 5, line 12 - line 29 see page 8, line 18 - page 12, line 17; figures 1-3	3,4
Y	WO,A,9 009 144 (PRECOR INCORPORATED) 23 August 1990	1,2,11, 12,13
A	see page 12, line 35 - page 13, line 38 see page 15, line 15 - page 16, line 8 see page 24, line 3 - page 26, line 11; figures 1-3,5,6	9,10
A	EP,A,0 245 039 (WESTINGHOUSE ELECTRIC CORPORATION) 11 November 1987 see page 8, line 11 - line 24	5-8,14, 15

* Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
24 APRIL 1992	15. 05. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	FONTENAY P.H.

1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9200298 SA 56476

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 24/04/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		EP-A-	0458896	04-12-91
		GB-A-	2228331	22-08-90
EP-A-0245039	11-11-87	JP-A-	63059606	15-03-88
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		US-A-	5032978	16-07-91